Exactech® Equinoxe® CTA Humeral Head
Traditional 510(k) – 510(k) Summary

MAY 17 2011

I. Submitter Information

Company: Exactech, Inc

Date: **March 11th, 2011**

Contact Person: Graham L. Cuthbert
Regulatory Affairs Specialist II
Telephone: (352) 327-4613
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II. Device Information

Proprietary Name: Exactech® Equinoxe® Cuff Tear Arthroplasty (CTA) Head

Common Name: Humeral Component

Classification Name: Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented (21 CFR 888.3650, Class II, Product Code KWT)
Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (21 CFR 888.3660, Class II, Product Code HSD)

III. Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Exactech Equinoxe, K042021
- DePuy Global Advantage Extended Humeral Head, K000575 & K082715
- Biomet Bio-Modular EAS Head, K030710 & K042321

IV. Device Description

The proposed Exactech Equinoxe CTA Humeral Head devices are humeral heads for use with the Equinoxe Shoulder System cleared via 510(k) K042021. Compared to predicate Equinoxe humeral heads, the proposed CTA Humeral Heads have an extended articular surface, designed to to contact the acromion in a rotator-cuff deficient patient.

V. Indications for Use

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

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Clinical indications for the PRIMARY (P), LONG (L) and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
√	√		congenital abnormalities in the skeletally mature
√			primary and secondary necrosis of the humeral head.
√		√	humeral head fracture with displacement of the tuberosities
√	√		pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
√	√		revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		√	displaced three-part and four-part upper humeral fractures
	√		spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		revision of failed previous reconstructions when distal anchorage is required
√	√		to restore mobility from previous procedures (e.g. previous fusion)
√	√	√	rotator cuff tear arthropathy

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

VI. Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

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- **Intended Use.** The Equinoxe CTA Humeral Head devices and predicate devices are intended for use in shoulder joint replacement and have similar indications for use statements.
- **Materials.** The Equinoxe CTA Humeral Head devices and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** The Equinoxe CTA Humeral Head devices and predicate device components are available in equivalent size ranges.
- **Sterilization processes.** The Equinoxe CTA Humeral Head devices and predicate devices are sterilized using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** The Equinoxe CTA Humeral Head devices and predicate devices conform to recognized performance standards for total shoulder joint replacement.

Substantial Equivalence Conclusion

Literature reviews, mechanical tests, simulated-use tests, and engineering analyses demonstrate the proposed Equinoxe CTA Humeral Head devices are substantially equivalent to the predicate devices. A summary of these tests and analyses are as follows:

- Cadaver and sawbones lab validation demonstrating the design features.
- Mechanical testing to verify CTA Humeral Head structural integrity and fixation properties.
- Clinical literature reviews of CTA devices and clinical failure modes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Mr. Graham Cuthbert
Regulatory Affairs Specialist
2320 Northwest 66th Court
Gainesville, Florida 32653

MAY 17 2011

Re: K110706
Trade/Device Name: Exactech Equinoxe Cuff Tear Arthropathy (CTA) Humeral Head
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: March 11, 2011
Received: March 14, 2011

Dear Mr. Cuthbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110706

Device Name: Exactech Equinoxe® CTA Humeral Head

INDICATIONS FOR USE:
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	√		spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
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glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

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Prescription Use __X__ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110706